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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,834	02/02/2004	Andrew F. Hall	5236-000471	9759
28997 7590 06/26/2009 HARNESS, DICKEY, & PIERCE, P.L.C 7700 Bonhomme, Suite 400 ST. LOUIS, MO 63105				
EXAMINER ANDERSON, GREGORY A				
ART UNIT		PAPER NUMBER		
3773				
MAIL DATE		DELIVERY MODE		
06/26/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/771,834

Applicant(s)

HALL ET AL.

Examiner

GREGORY ANDERSON

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2009.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-19, 29 and 30 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 6-19, 29 and 30 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
4) ☐ Interview Summary (PTO-413)
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____
Paper No(s)/Mail Date _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claim 7 is rejected under 35 U.S.C. 102(e) as being anticipated by Howard 6,129,685.

Howard discloses a system comprising: a sheath 1103, having a sheath body; a lumen extending through the sheath from the proximal to the distal end; a catheter 1105 having a catheter body and a distal end that terminates in a distal tip; an energy source 1107 coupled to the distal tip; a magnetically active element 1104 forming a portion of the distal end of the sheath body sufficient to align the distal tip of the sheath generally with respect to the direction of an applied magnetic field (Fig. 27B); and a magnet outside the body that applies a magnetic field of sufficient strength to align the magnetically active element with respect to the direction of the applied magnetic field to orient the distal end of the sheath (Col. 11 ll. 31-38).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 6, 13 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson 5,845,646.

Lemelson discloses a system comprising: a catheter having a catheter body having a proximal end and a distal end terminating in distal tip, wherein the catheter body and the is capable of being mechanically pushed to advance the distal tip; an energy source coupled to said distal tip (Col. 14 ll. 12-25); a magnetically active element located proximate said distal tip of said catheter body; and a magnet outside the body that applies a magnetic field to orient the distal tip of the catheter such that the catheter advances in a direction determined by the magnetic orientation of the distal end of the sheath (Col. 13 l. 60- Col. 14 l. 11).

However, Lemelson does not disclose a sheath, having a sheath body, said sheath body having a proximal end and having a distal end; a lumen extending through said sheath body from said proximal end to said distal end.

The Examiner takes official notice that it is notoriously old and well known in the art to provide a sheath having a proximal and distal ends over a catheter.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Lemelson by providing a sheath over the catheter of Lemelson in order to facilitate easier mobility of the catheter through the vasculature.

Regarding claims 13 and 17-19: Lemelson further discloses utilizing ultrasonic imaging (Col. 1 ll. 7-29), laser imaging (Col. 14 ll. 18-20), and a fluid directing element (Col. 14 ll. 20-25).

4. Claims 8-12, 14-16, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson in view of substitution of known equivalents.

Lemelson discloses the invention essentially as claimed as discussed in claim 6 above. Lemelson further discloses using eddy currents of the magnetic field to heat a magnetic element (Col. 14 ll. 33-38).

However, Lemelson does not disclose using radio frequency, laser energy applied to a thermally conductive element, or resistance heating elements for heating.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Lemelson by substituting the magnetically driven heating for optical laser energy or resistance heating elements and electrical energy since it has been held that the selection of a known component is obvious when it does not produce a new or unexpected result; *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Response to Arguments

Applicant's arguments filed 10 April 2009 have been fully considered but they are not persuasive. Applicant argues that Lemelson reference refers only to magnetic gradient and not magnetic field, and that Applicant's device orients itself to the magnetic field while Lemelson's does not. Examiner disagrees; the Lemelson reference discloses that the position of the catheter can be adjusted by varying the direction and magnitude

of the externally-applied magnetic field (Col. 13 l. 66-Col. 14 l. 1), the magnetically active element will, by the nature of magnetic forces, align itself with a magnetic field that is stationary, to adjust the alignment, the magnetic field must be adjusted, which also due to the nature of magnetic fields causes a gradient. Thus, both the Lemelson device and Applicant's own invention will see a gradient force when reorienting the catheter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY ANDERSON whose telephone number is (571)270-3083. The examiner can normally be reached on Mon-Thurs 9:30AM-3PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory A Anderson/

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773